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November 30, 1999

Document Branch HFA 305
Food & Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Reference Number: 97N-484S

To whom it may concern:

Regarding FDA proposal to regulate allograft tissue. In response to a memo presented to me informing me of the FDA's proposal to regulate allograft tissue as medical devices, I only have one concern in common at this time and that is these products of fibular struts, femoral struts, tibial struts, rings, dowels and other types of allograft material are commonly used in cervical and lumbar fusion surgery. If plans are to be regulation for these devices, they should make some provisions for these devices not to be limited during the process because these are used very commonly in our practice of Neuro-Surgery in Battle Creek, MI. To limit these devices could potentially impact patient care significantly to the point of actually withholding appropriate medical care if these devices were not available.

Therefore, as far as ensuring the safety to the public of these devices, I am all for that. But if these devices would be limited and not be made available on a regular basis, then I would object to that.

Sincerely,



Philip J. Hlavac, M.D.
PH:kjk 12/02/99

97N-484S

CS8



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November 29, 1999

**FDA PROPOSAL TO REGULATE
ALLOGRAFT TISSUE**

Dear Doctor:

I am writing to you today to **inform** you about another proposed **FDA** regulation that appeared in the **September 30, 1999**, issue of the **Federal Register**. *The wording* used in the proposed **FDA** regulation, if accepted, could allow FDA to regulate some types of **allograft** as medical devices.

As you are aware, bone banks currently provide bone as tissue, for which the **FDA** regulates the safety. However, bone banks likely do not have the resources or the expertise to satisfy the FDA's pre-market requirements, such as sponsoring **clinical** trials **and** submitting lengthy regulatory documents. This may lead to a curtailed supply of bone products on which you rely for treating patients. The potential implications of FDA's regulatory actions with this proposal are staggering.

As part of the rule-making process, the public is allowed to comment on such proposals. I encourage you to do so, since you probably use banked tissues in your practice. Public comments must be submitted by **December 29, 1999, to the** following address:

Document Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Please reference **Docket No. 97N-484S** so that your comments will be filed properly. If you have any questions or need additional information, including a copy of the proposal with the specific definitions, please do not hesitate to call my office at (800) 763-2667. Thank you for your interest **in** this issue.

Best regards,

Ron Pickard

Neuro-Surgical Services, P.C.

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